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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,128	06/30/2000	GRAHAM FRANCOIS DUIRS	42341-350041	2910

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EXAMINER	
GILBERT, ANDREW M	
ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
01/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/529,128	DUIRS, GRAHAM FRANCOIS	
	Examiner	Art Unit	
	ANDREW M. GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3-5, 8-9, 11, 14, 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,8,9,11,14 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/15/2008 has been entered.

Acknowledgments

1. This office action is in response to the reply filed on 9/15/2008.

2. In the reply, the applicant amended claims 1, 4 and 21. Claims 2, 6-7, 10, 12-13, 15-20 were cancelled

3. Thus, claims 1, 3-5, 8-9, 11, 14, 21 are pending for examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4-5, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiller et al (4369783). Hiller et al discloses an internal substance delivery device for insertion into a body cavity (Summary), the device includes a support frame (1) having

at least two resilient arms (two biased angled arms of 1 that connect to 4a and 4a) which retain the inserted internal substance delivery device against a mucosal membrane of the body cavity (col 1, lns 12-45; col 2, lns 66-col 3, lns 7), wherein each resilient arm is capable of receiving and releasing a separate pod (4a, 4a; Fig 1-17) capable of releasing a drug contained within a matrix of the pod into the body cavity (Figs 1-17; 4a, col 4, lns 37-col 5, lns 51), and wherein each distal end of the at least two resilient arms and pods attached to the arms are biased outward from a central section (Figs 1-17; central section of 1 before angled curve (see Fig 1)) of the support frame; wherein at least one of the pods is flexibly attached to a corresponding arm by a ball and socket mechanism (Fig 1-17; 4a, 3; col 3, lns 8-11) allowing full movement or 3-dimensional movement of the pod with respect to the support frame and enabling the internal substance delivery device to contact the mucosal membrane within the body cavity (col 1, lns 12-45; col 2, lns 66-col 3, lns 20); wherein the substance is released from the pod through osmosis (col 5, lns 30-42); wherein the pod is rounded (col 4, lns 22-25); wherein at least one of the pods is flexibly attached to a corresponding arm (Fig 1-17; col 3, lns 8-11). Additionally, see Response to Arguments below.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiller et al. Hiller et al discloses the invention substantially as claimed except for expressly disclose the support frame being made out of nylon. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the support frame out of nylon because the Applicant has not disclosed that making the support frame out of nylon provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the support frame material of Anderson et al because the material performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify Hiller et al to obtain the invention as specified in claim 11.

8. Claims 3 and 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiller et al in view of Anderson et al (5816248). Hiller et al discloses the invention substantially as claimed except for expressly disclosing wherein the device is an intra-vaginal release device for insertion within the vagina. However, the device of Hiller et al is a prophylactic device structurally shaped and capable of vaginal placement. Anderson et al teaches that it is known to have an intra-vaginal release device for insertion within the vagina (Abstract, col 3, lns 52-67; col 4, lns 18-col 5, lns 37) for the purpose of delivering an agent to the urogenital tract. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Hiller et al with the intra-vaginal device for insertion within the

vagina as taught by Anderson et al for the purpose of delivering an agent to the urogenital tract.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiller et al in view of Anderson et al (5816248). Hiller et al discloses the invention substantially as claimed except for expressly disclosing wherein the support frame is in the form of a wish bone. Anderson et al teaches that it is known to have wherein the support frame is in the form of a wish bone (Fig 3) for the purpose of implantable placement in the urogenital tract. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the support frame as taught by Hiller et al with the wish bone shaped support frame as taught by Anderson et al for the purpose of implantable placement in the urogenital tract.

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiller et al in view of Anderson et al (5816248). Hiller et al discloses the invention substantially as claimed except for expressly disclosing wherein the support frame includes a locator. Anderson et al teaches that it is known to have wherein the support frame includes a locator (68, Abstract, col 3, lns 52-57; col 4, lns 18-col 5, lns 37) for the purpose of correct positioning of the device inside the vaginal region. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the support frame as taught by Hiller et al with the locator as taught by Anderson et al for the purpose of correct positioning of the device inside the vaginal region.

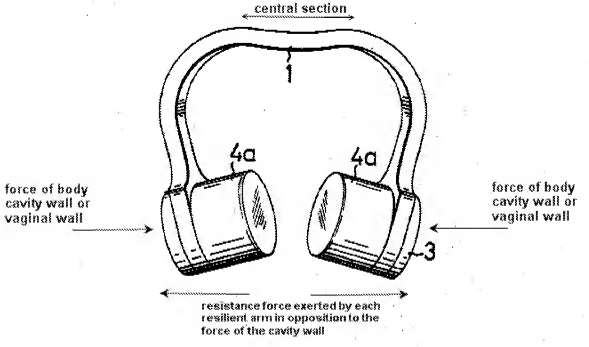
Response to Arguments

11. Applicant's arguments filed 4/28/2008 have been fully considered but they are not persuasive.

12. The applicant argues that:

i. Hiller et al does not disclose each distal end of the two resilient arms and pods attached to the arms being biased outward from a central section of the support frame. Rather, the distal ends of each of the arms are inclined towards each other and the pods face each other. The pods cannot be biased outward if they face each other.

13. In response to the applicant's argument (i), the Examiner notes that as claimed "each distal end of the at least two resilient arms and pods attached to the arms are biased outward from a central section of the support frame" (emphasis added).



14. Webster's defines "biased" as an inclination of temperament or outlook. In the present case, the baseline structure of the device when it is not in use is shown above. The applicant is correct that the arms are inclined towards each other and the pods face each other. The Examiner contends that because the arms are resilient, with respect to the central section of the support frame the arms are fully capable of being biased in two directions. The first, inwards towards each other like a clip, is the embodiment discussed in length in Hiller. During use, the arms are spread outward apart from each other to insert into the nasal septum and then released so that they return to their normal state clamping on the nasal septum and securing the device in the cavity. The second, is the reverse. The device of Hiller is fully capable of being inserted into a body cavity, such as the vagina but for exemplary purposes lets assume the nasal cavity – a cavity smaller in size than the device's non-use structural state, to an extent where the device is squished, the resilient arms are pushed inwards decreasing the width of the device during insertion and then released. The resilience of the arms will attempt to return to their standard state, an inclination to return to its non use state. In such an attempt, the arms will be biased outwards attempting to return to the standard state and exerting a force on the cavity wall securing the device in place.

15. Hiller et al does not a pictorial embodiment of the ball and socket pods disclosed in col 3, lns 8-11; however, the pods are attached to the arms which are biased outward and are thus also biased outwards and thus meet the claim limitations. Further, the ball and socket pods allow for 3-d motion of the pods and are fully capable of allowing the pods to contact the walls of the body cavity or vagina.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767